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Effect of a Patient-Centered Decision Support Tool on Rates of Trial of Labor After Previous Cesarean Delivery
The PROCEED Randomized Clinical Trial

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IMPORTANCE Reducing cesarean delivery rates in the US is an important public health goal; despite evidence of the safety of vaginal birth after cesarean delivery, most women have scheduled repeat cesarean deliveries. A decision support tool could help increase trial-of-labor rates.

OBJECTIVE To analyze the effect of a patient-centered decision support tool on rates of trial of labor and vaginal birth after cesarean delivery and decision quality.

DESIGN, SETTING, AND PARTICIPANTS Multicenter, randomized, parallel-group clinical trial conducted in Boston, Chicago, and the San Francisco Bay area. A total of 1485 English- or Spanish-speaking women with 1 prior cesarean delivery and no contraindication to trial of labor were enrolled between January 2016 and January 2019; follow-up was completed in June 2019.

INTERVENTIONS Participants were randomized to use a tablet-based decision support tool prior to 25 weeks' gestation (n=742) or to receive usual care (without the tool) (n=743).

MAIN OUTCOMES AND MEASURES The primary outcome was trial of labor; vaginal birth was the main secondary outcome. Other secondary outcomes focused on maternal and neonatal outcomes and decision quality.

RESULTS Among 1485 patients (mean age, 34.0 [SD, 4.5] years), 1470 (99.0%) completed the trial (n = 735 in both randomization groups) and were included in the analysis. Trial-of-labor rates did not differ significantly between intervention and control groups (43.3% vs 46.2%, respectively; adjusted absolute risk difference, −2.78% [95% CI, −7.80% to 2.25%]; adjusted relative risk, 0.94 [95% CI, 0.84-1.05]). There were no statistically significant differences in vaginal birth rates (31.8% in both groups; adjusted absolute risk difference, −0.04% [95% CI, −4.80% to 4.71%]; adjusted relative risk, 1.00 [95% CI, 0.86-1.16]) or in any of the other 6 clinical maternal and neonatal secondary outcomes. There also were no significant differences between the intervention and control groups in the 5 decision quality measures (eg, mean decisional conflict scores were 17.2 and 17.5, respectively; adjusted mean difference, −0.38 [95% CI, −1.81 to 1.05]; scores >25 are considered clinically important).

CONCLUSIONS AND RELEVANCE Among women with 1 previous cesarean delivery, use of a decision support tool compared with usual care did not significantly change the rate of trial of labor. Further research may be needed to assess the efficacy of this tool in other clinical settings or when implemented at other times in pregnancy.

Editorial page 2145

Supplemental content

CME Quiz at jamacmelookup.com and CME Questions page 2190

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The US cesarean delivery rate increased from 20.7% in 1996[1] to 31.9% in 2018,[2] accompanied by substantial increases in maternal morbidity.[3,4] Safely decreasing the cesarean delivery rate is therefore an important public health goal.[5] Part of the increased cesarean delivery rate is attributable to the decreased frequency with which women undergo trial of labor after previous cesarean delivery, which caused rates of vaginal birth after cesarean delivery to decrease from 28.3% in 1996[1] to 13.3% in 2018.[2] Numerous factors have been posited as contributing to this decline, including the decreased number of hospitals and clinicians willing to offer trial of labor after cesarean.[6] However, even when available, the proportion of women who undergo this delivery approach has decreased.[7]

A National Institutes of Health consensus conference statement noted that the informed consent process for trial of labor after cesarean delivery and elective repeat cesarean delivery "should be evidence-based, minimize bias, and incorporate a strong emphasis on the values and preferences of pregnant women" and recommended "collaboration to refine, validate, and implement decision-making and risk assessment tools" to accomplish that goal.[8] However, a review of planned cesarean delivery across multiple contexts suggests limited implementation of shared decision-making in clinical practice, with many women lacking the information they need to make informed decisions.[9]

This randomized trial tested the hypothesis that women eligible for trial of labor after cesarean delivery would be more likely to opt for this delivery approach, have a vaginal delivery, and experience better decision quality if they had the opportunity to use a decision support tool that offered consistent and reliable information regarding the processes and potential outcomes of trial of labor after cesarean delivery and elective repeat cesarean delivery, included explicit consideration of their values and preferences, and provided a personalized assessment of their likelihood of having a vaginal birth if they underwent trial of labor.

Key Points

Question Does use of a patient-centered decision support tool increase the likelihood of trial of labor after previous cesarean delivery?

Findings In this randomized clinical trial of 1485 women with previous cesarean delivery, use of a decision support tool compared with usual care resulted in rates of trial of labor of 43.3% vs 46.2%, a difference that was not statistically significant.

Meaning The use of this decision support tool did not affect rates of trial of labor, but further research may be needed to assess its efficacy in other clinical settings.

Methods

Trial Design

The Prior Cesarean Decision (PROCEED) study was a multicenter, randomized, parallel-group clinical trial conducted at 3 academic medical centers and 2 community sites. Participants were not masked to the intervention, but primary and secondary outcomes were assessed by study staff unaware of group assignment. The protocol was approved by the institutional review board at each site, and all participants provided written informed consent prior to the enrollment interview. Details of the trial protocol and statistical analysis plan are available in Supplement 1.

Participants and Procedures

We recruited English- or Spanish-speaking women who were eligible for trial of labor from prenatal clinics at the University of California, San Francisco; Massachusetts General Hospital in Boston; Northwestern University Medical Center in Chicago; St Luke's Women's Clinic in San Francisco; and Marin Community Clinic in San Rafael, California. Eligibility criteria included 1 prior cesarean delivery, no prior vaginal birth after cesarean delivery, gestational age between 12 weeks 0 days and 24 weeks 6 days, singleton gestation, and no known absolute contraindication to trial of labor (eg, prior classical or T-incision cesarean delivery, prior uterine surgery). We enrolled participants during this gestational age range to ensure that the decision tool was used when it could inform longitudinal discussions regarding delivery approach and before final decisions were likely to have been made. This process is consistent with the American College of Obstetricians and Gynecologists recommendations suggesting initiating discussions about delivery approach in the context of prior cesarean delivery early in pregnancy.[10]

Research staff identified potentially eligible participants by reviewing appointment records. Women who were eligible and interested provided informed consent and completed an interviewer-administered questionnaire. Because rates of cesarean delivery differ by race/ethnicity,[1] self-reported race and ethnicity were obtained, with participants able to indicate, through closed- and open-ended questions, the group(s) with which they most identified. Participants were then randomized to use or not use a prior cesarean delivery decision support tool (PROCEED Decision Support Tool; see eFigure in Supplement 2) on an electronic tablet. The computer-generated allocation sequence used randomly permuted blocks of 8, 10, and 12, stratified by language and recruitment site. Both groups otherwise received usual care at their sites, including counseling by a clinician regarding delivery approach. No decision support tools for use by patients were in place at any of the sites, and no specific interactions with clinicians were required by the study protocol.

Between 34 weeks 0 days and 37 weeks 6 days of gestation, patient-reported outcomes were assessed during a telephone interview conducted by research staff unaware of group assignment. Delivery approach (trial of labor or elective repeat cesarean) and mode (vaginal or cesarean) were ascertained postpartum via medical record review conducted by clinician investigators, who also were unaware of the randomization group. Participants who delivered at an outside institution were contacted by telephone to collect self-reported pregnancy outcomes as well as to obtain their permission for release of their medical records.

Participants were enrolled from January 2016 through January 2019 and followed up until they completed their

postpartum hospital stay, the last of which occurred in June 2019. They received $40 as remuneration at completion of both the baseline and follow-up interviews.

Intervention

The decision support tool was developed using a systematic process based on the International Patient Decision Aids Standards Collaboration recommendations.[11] Published data regarding the potential outcomes of trial of labor after cesarean delivery and elective repeat cesarean delivery, as well as prior work in identifying preference-based predictors of trial of labor after cesarean delivery[12] and developing interactive multimedia decision tools,[13] informed the tool's content and framework. The tool was designed to be integrated into clinical care to inform the conversations between clinicians and patients and encourage shared decision-making.

Sixty-six women with prior cesarean delivery who were pregnant or had given birth in the last 3 years participated in focus groups and cognitive debriefings during an iterative development process to ensure acceptability, balance, clarity, and appropriateness of the information presented, design, and interactive aspects of the decision tool. Certified interpreters and native Spanish speakers forward- and back-translated the tool, which was iteratively tested among Spanish speakers.

The final version of the decision tool consists of approximately 10 minutes of content, with topic-specific information, engaging graphics, and user-specific risk information generated using a validated prediction calculator that incorporates patient characteristics known during early prenatal care.[11] To improve user experience, "learn more" buttons are included to allow additional content to be accessed if desired. The tool also includes values clarification exercises, which are recommended to increase patient engagement and to optimize decision support by targeting intuition and deliberation.[14] These exercises focus on factors identified as important to decision-making in this context[12] (eFigure in Supplement 2).

Women randomized to the control group completed the baseline and follow-up questionnaires but had no intervention. In both groups, all care was at the discretion of the participants' clinicians.

Outcomes

The primary outcome for this study was delivery approach (trial of labor after cesarean delivery or elective repeat cesarean delivery); vaginal birth was the major secondary outcome. Other secondary outcomes focused on maternal outcomes (death, major or minor morbidity, and third- or fourth-degree lacerations), perinatal outcomes (death, hypoxic ischemic encephalopathy, respiratory morbidity, and neonatal intensive care unit admission), and decision quality (decisional conflict, knowledge, shared decision-making, decision efficacy, and decision satisfaction).

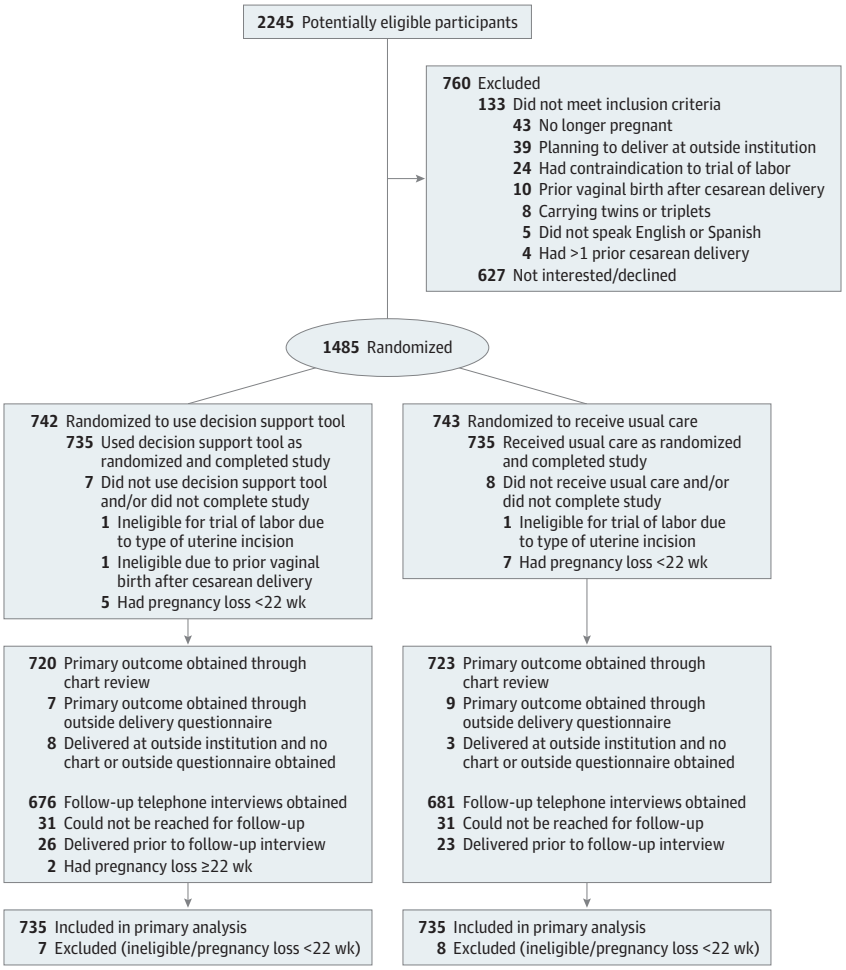
To measure decisional conflict, we used the Decisional Conflict Scale,[15] a validated instrument that is recommended for the assessment of decision quality by the International Patient Decision Aid Standards Collaboration.[16] This 16-item measure generates an overall score and 5 subscale scores ranging from 0 to 100, with scores greater than 25 indicating clinically important decisional conflict.[17] A review of 253 studies using this scale reported mean baseline scores in studies of mode of delivery of 35.2, which decreased to 23.1 after use of a decision tool.[18] Knowledge about trial of labor after cesarean delivery and elective repeat cesarean delivery was assessed using a modified version of an 8-item questionnaire.[19] Shared decision-making was measured using the 9-item Shared Decision Making Questionnaire (SDM-Q-9), a psychometrically evaluated tool,[20] and decision self-efficacy was measured with the Decision Self-efficacy Scale, an 11-item instrument in which participants rate their confidence in the decision-making process.[21] Both scales range from 0 to 100, with higher scores denoting more shared and self-efficacious decisions. A recent review reported mean SDM-Q-9 scores of 42 to 75 in published studies[22] while a recent US study using the Decision Self-efficacy Scale noted a mean score of 76.7.[23] Decision satisfaction was assessed using the Satisfaction With Decision Scale, a 6-item instrument designed to measure global satisfaction with a health decision; scores range from 1 to 5, with a reported mean of 3.9 in the validation study.[24] Validated Spanish-language instruments were used when available; other instruments were forward- and back-translated by native Spanish speakers and certified interpreters.

Statistical Analysis

Our primary hypothesis was that women randomized to use the decision support tool would be more likely to undergo trial of labor than those in the control group. A review of historical data from the study sites suggested a combined rate of trial of labor after cesarean delivery of approximately 33%; we assumed this would be the rate in the control group. We calculated that a planned enrollment of 1320 women with approximately 5% loss to follow-up would provide 80% power at $P < .05$ for a between-group difference in trial of labor after cesarean delivery rate of at least 8%, which would approximate rates of trial of labor after cesarean delivery achieved in the past, a clinically meaningful target.[1] Participants were analyzed by randomization group after excluding women found to be ineligible after randomization or who experienced a pregnancy loss prior to 22 weeks' gestation, as they undergo a different decision-making process in which an elective repeat cesarean delivery is rarely a recommendation, and dilation and evacuation, which is neither trial of labor nor elective repeat cesarean delivery, is a reasonable treatment choice.

For our primary outcome (trial of labor) and major secondary outcome (vaginal birth), we calculated the proportion of women with the outcome by treatment group and estimated an absolute risk difference and relative risk for the outcome between treatment groups. Based on established recommended practices, absolute risk differences were estimated using linear regression models and relative risks were estimated using Poisson regression models with robust standard errors,[25] adjusting for recruitment site and interview language, because these factors defined randomization strata.[26] Analyses of differences between treatment groups for the maternal and neonatal morbidity outcomes were evaluated in the same manner. For trial of labor and vaginal birth, we also examined interactions of treatment group with a priori–defined factors of site, race/ethnicity, and language by adding an interaction term

Figure. Participant Flow in the Prior Cesarean Decision (PROCEED) Randomized Clinical Trial



for treatment group and the factor to the primary models described above. For continuous outcomes (eg, decisional conflict), we calculated the mean score by treatment group and estimated differences using linear regression models, again adjusting for recruitment site and language of interview. We also conducted a prespecified sensitivity analysis of trial of labor excluding women who developed contraindications (breech presentation and placenta previa) that was otherwise identical to the primary analysis. In addition, we performed 2 post hoc analyses. In the first analysis, we tested for differences in rates of trial of labor by the gestational age when the decision support tool was viewed among women in the intervention group, fitting a Poisson regression model with gestational age and adjustment for site and language. In the second analysis, we handled missing data by applying multiple imputation with 100 imputed data sets using the Markov chain Monte Carlo method,[27] and then repeated all regression analyses to determine whether using multiple imputation altered the results.

All analyses used SAS software version 9.4 (SAS Institute Inc). Statistical significance was defined as a 2-sided $P < .05$. Because of the potential for type I error due to multiple comparisons, findings for analyses of secondary end points other than vaginal birth after cesarean delivery should be interpreted as exploratory.

Results

Of 2245 potentially eligible participants approached, 133 (5.9%) did not meet inclusion criteria and 627 (27.9%) declined to participate (**Figure**). The remaining 1485 (66.1%) were randomized, 742 (50.0%) to the intervention group and 743 (50.0%) to the control group. Fifteen (1.0%) were excluded from final analysis (7 in the intervention group and 8 in the control group) because they experienced a pregnancy loss prior to 22 weeks' gestation (n = 12 [0.8%]) or were found to be ineligible after randomization (n = 3 [0.2%]; 2 after discovery of uterine incisions contraindicating trial of labor on subsequent receipt of operative delivery report and 1 after discovery that a prior vaginal birth occurred after instead of before the prior cesarean delivery).

The 1470 women included in the analytic data set (735 in each group) comprised a racially/ethnically diverse sample (**Table 1**): 54.8% self-identified as white, 16.9% as Latina,

Table 1. Baseline Participant Characteristics and Delivery Approach Inclination[a]

Characteristics	Intervention group (n = 735)[b]	Control group (n = 735)[b]
Sociodemographic characteristics		
Age, mean (SD), y	34.1 (4.6)	34.0 (4.5)
Race or ethnic group		
White	394 (53.6)	411 (55.9)
Latina	124 (16.9)	124 (16.9)
Asian or Pacific Islander	110 (15.0)	106 (14.4)
Black	64 (8.7)	52 (7.1)
Biracial or multiracial/multiethnic	23 (3.1)	25 (3.4)
Other[c]	20 (2.7)	17 (2.3)
Opted for Spanish-language interview	55 (7.5)	54 (7.4)
Highest level of education		
Less than high school diploma	21 (2.9)	21 (2.9)
High school graduate or GED	55 (7.5)	49 (6.7)
Some college	87 (11.8)	83 (11.3)
College graduate	280 (38.1)	275 (37.4)
Professional or graduate degree	292 (39.7)	307 (41.8)
Married or living with partner	690 (93.9)	685 (93.2)
Approximate yearly household income, $	n = 706	n = 702
<25 000	56 (7.9)	49 (7.0)
25 000-50 000	65 (9.2)	67 (9.5)
50 001-100 000	99 (14.0)	101 (14.4)
100 001-200 000	224 (31.7)	223 (31.8)
>200 000	262 (37.1)	262 (37.3)
Health insurance	n = 734	n = 735
Public	144 (19.6)	130 (17.7)
Private	587 (80.0)	598 (81.4)
Other	3 (0.4)	7 (1.0)
Recruitment site		
University of California, San Francisco	192 (26.1)	193 (26.3)
Marin Community Clinic, San Rafael, California	26 (3.5)	25 (3.4)
St Luke's Women's Clinic, San Francisco	18 (2.5)	18 (2.5)
Massachusetts General Hospital, Boston	274 (37.3)	278 (37.8)
Northwestern University Medical Center, Chicago	225 (30.6)	221 (30.1)
Clinical characteristics		
Prepregnancy body mass index, mean (SD)[d]	26.5 (6.4) [n=712]	26.4 (6.0) [n=714]
Prior vaginal delivery	39 (5.4) [n=727]	50 (6.9) [n=728]
Prior cesarean delivery primary indication	n=717	n=724
Arrest disorder[e]	320 (44.6)	322 (44.5)
Fetal indication[f]	345 (48.2)	364 (50.3)
Maternal clinical indication[g]	44 (6.1)	35 (4.8)
Maternal request	8 (1.1)	3 (0.4)
Prior cesarean delivery incision type[h]	682	687
Low transverse	682 (100.0)	683 (99.4)
Low vertical	0	4 (0.6)
Delivery approach inclination[i]		
Definitely a repeat cesarean delivery	150 (20.4)	149 (20.3)
Probably a repeat cesarean delivery	146 (19.9)	143 (19.5)
Not sure/don't know	100 (13.6)	83 (11.3)
Probably try to have a vaginal delivery	126 (17.1)	157 (21.4)
Definitely try to have a vaginal delivery	213 (29.0)	203 (27.6)

Abbreviation: GED, general education development certificate.

[a] Data are reported as No. (%) of participants unless otherwise indicated.

[b] Data with denominators other than 735 participants are indicated in respective rows.

[c] Includes Middle Eastern, North African, South Asian, Caribbean, Turkish, non-Latina South American, and Jewish (as self-reported by participants).

[d] Body mass index is calculated as weight in kilograms divided by height in meters squared.

[e] Includes cephalopelvic disproportion, arrest of dilation, arrest of descent, active phase arrest, and failed induction.

[f] Includes nonreassuring fetal status, oligohydramnios, breech presentation, multiple gestations, macrosomia, prior shoulder dystocia, and abruption.

[g] Includes preeclampsia, placenta or vasa previa, and other medical conditions.

[h] Women without documentation regarding prior uterine incision were eligible if they met other criteria. Missing data include those for which prior incision type was either missing or explicitly recorded as unknown.

[i] Participant responses to the question "At this point, which approach to your delivery are you leaning toward?"

Table 2. Primary, Major Secondary, and Other Clinical Outcomes

Outcomes	No./total (%)		Adjusted absolute risk difference, % (95% CI)[a]	*P* value	Adjusted relative risk (95% CI)[b]	*P* value
	Intervention group (n = 735)	Control group (n = 735)				
Primary outcome (delivery approach)						
Trial of labor after cesarean delivery	315/727 (43.3)	338/732 (46.2)	-2.78 (-7.80 to 2.25)	.28	0.94 (0.84-1.05)	.28
Major secondary outcome (delivery mode)						
Vaginal birth after cesarean delivery for entire group	231/727 (31.8)	233/732 (31.8)	-0.04 (-4.80 to 4.71)	.99	1.00 (0.86-1.16)	.99
Vaginal birth after cesarean delivery among women who underwent trial of labor	231/315 (73.3)	233/338 (68.9)	4.33 (-2.59 to 11.25)	.22	1.06 (0.96-1.17)	.22
Other secondary maternal clinical outcomes						
Major maternal morbidity	19/720 (2.6)	23/723 (3.2)	-0.55 (-2.28 to 1.18)	.54	0.83 (0.46-1.51)	.54
Uterine rupture	4/721 (0.6)	5/725 (0.7)				
Hysterectomy	2/720 (0.3)	1/724 (0.1)				
Surgical injury	15/720 (2.1)	21/723 (2.9)				
Maternal death	0	0				
Minor maternal morbidity	36/719 (5.0)	36/722 (5.0)	0.002 (-2.24 to 2.24)	>.99	1.00 (0.64-1.56)	>.99
Blood transfusion	26/720 (3.6)	29/723 (4.0)				
Postpartum febrile morbidity	13/719 (1.8)	10/722 (1.4)				
Third- or fourth-degree laceration	16/720 (2.2)	12/723 (1.7)	0.56 (-0.86 to 1.99)	.44	1.34 (0.64-2.81)	.44
Perinatal outcomes						
Perinatal death or hypoxic-ischemic encephalopathy	8/720 (1.1)	4/722 (0.6)	0.55 (-0.39 to 1.49)	.25	2.00 (0.60-6.62)	.26
Neonatal death[c]	2/720 (0.3)	0				
Intrauterine fetal demise[d]	4/720 (0.6)	0				
Hypoxic-ischemic encephalopathy	2/720 (0.3)	4/722 (0.6)				
Neonatal respiratory morbidity[e]	67/719 (9.3)	68/721 (9.4)	-0.11 (-3.06 to 2.84)	.94	0.99 (0.72-1.35)	.94
Neonatal intensive care unit admission	98/720 (13.6)	87/722 (12.1)	1.55 (-1.90 to 4.99)	.38	1.13 (0.86-1.48)	.38

[a] Intervention effects are quantified as absolute risk differences (difference in the percentage with the outcome in each group), estimated using linear regression models adjusted for recruitment site and language of interview.

[b] Intervention effects are quantified as relative risks, estimated from Poisson regression models adjusted for recruitment site and language of interview.

[c] Both neonatal deaths were after cesarean delivery.

[d] All 4 stillbirths were antepartum intrauterine fetal demises prior to admission to the labor and delivery units (ie, none were intrapartum deaths); all stillborn neonates were delivered vaginally.

[e] Neonatal respiratory morbidity was defined as requirement for respiratory support (supplemental oxygen, continuous positive airway pressure, or intubation).

14.7% as Asian or Pacific Islander, 7.9% as black, and the remainder as biracial or multiracial/multiethnic (3.3%) or "other" (2.5%). Among the 248 Latina participants, 42.7% completed study activities in Spanish. The participants' mean age was 34.0 [SD, 4.5] years; most were college graduates (78.5%), were married or living with their partner (93.5%), and had private insurance (80.7%). A total of 6.1% had experienced a vaginal delivery prior to their cesarean delivery; prior cesarean deliveries were most commonly for fetal indications (49.2%) or arrest disorders (44.6%). The participants varied in their delivery approach inclinations at baseline, with 40.0% indicating elective repeat cesarean delivery and 47.6% indicating trial of labor. No characteristics differed by randomization group.

A total of 44.8% of the participants underwent trial of labor (**Table 2**). This percentage did not statistically significantly differ by randomization group (43.3% in the intervention group vs 46.2% in the control group; adjusted absolute risk difference, -2.78% [95% CI, -7.80% to 2.25%]; adjusted relative risk, 0.94 [95% CI, 0.84-1.05]). Vaginal birth rates also were not statistically significantly different (31.8% in both groups; adjusted absolute risk difference, -0.04% [95% CI, -4.80% to 4.71%]; adjusted relative risk, 1.00 [95% CI, 0.86-1.16]). None of the other maternal or perinatal outcomes differed statistically significantly by randomization group (see eTable 1 in Supplement 2 for information on labor management).

Decision quality also did not differ statistically significantly between groups (**Table 3**). In general, study participants had mean decisional conflict scores that were well below the threshold for clinically important decisional conflict[18] and did not differ statistically significantly between groups (17.2 vs 17.5; adjusted mean difference, -0.38; 95% CI, -1.81 to 1.05). Mean knowledge scores were the same in both groups (5.0). Shared decision-making, decision self-efficacy, and decisional satisfaction mean scores were high in comparison with values reported in the published literature and not significantly different between groups.

Prespecified interaction analyses showed no statistically significant effect modification between group assignment and trial of labor or vaginal birth by site, language, or race/ethnicity ($P \geq .26$ for all interactions); however, power was lower for these interactions, limiting the strength of this

Table 3. Participant-Reported Decision Quality Outcomes[a]

Outcomes	Mean (SD) [No.] Intervention group (n = 735)	Control group (n = 735)	Adjusted mean difference (95% CI)[b]	P value
Decisional conflict[c]				
Overall decisional conflict	17.2 (12.9) [671]	17.5 (13.9) [675]	-0.38 (-1.81 to 1.05)	.60
Uncertainty subscale	24.6 (21.5) [675]	25.0 (22.2) [680]	-0.49 (-2.81 to 1.83)	.68
Informed	13.5 (12.2) [675]	13.8 (13.6) [680]	-0.42 (-1.77 to 0.93)	.54
Values clarity	17.2 (15.4) [672]	17.2 (15.8) [680]	0.01 (-1.64 to 1.66)	.99
Support	12.3 (14.5) [674]	13.7 (16.5) [679]	-1.46 (-3.10 to 0.18)	.08
Effective decision	23.8 (20.5) [673]	23.4 (20.5) [677]	0.30 (-1.89 to 2.49)	.79
Knowledge[d]	5.0 (1.8) [676]	5.0 (1.7) [681]	0.01 (-0.16 to 0.19)	.88
Shared decision-making[e]	74.4 (14.9) [664]	74.8 (15.9) [672]	-0.34 (-1.96 to 1.27)	.68
Decision self-efficacy[f]	90.7 (12.3) [670]	90.3 (12.2) [672]	0.36 (-0.94 to 1.66)	.59
Decision satisfaction[g]	4.62 (0.59) [675]	4.65 (0.54) [679]	-0.03 (-0.09 to 0.03)	.39

[a] Decision quality is defined as knowledge about trial of labor after cesarean delivery and elective repeat cesarean delivery, decisional conflict (overall and by subscale), shared decision-making regarding delivery approach, decision self-efficacy, and decision satisfaction.

[b] Intervention effects are quantified as differences between groups in the mean value for each scale, estimated using linear regression models that adjusted for recruitment site and language of interview.

[c] Decisional Conflict Scale total and subscale scores range from 0 to 100, with higher scores indicating feeling more conflict, less informed, less certainty, less clear about personal values for benefits and risks/adverse effects, less supported in decision-making, and more that the decision was bad. Scores above 25 on the Decisional Conflict Scale are considered clinically important.

[d] Knowledge scores range from 0 to 8, with higher scores indicating greater knowledge. A mean score of 5 indicates participants on average answered 62.5% of questions correctly.

[e] Shared Decision Making Questionnaire scores range from 0 to 100, with higher scores indicating more shared decision-making. Scores in the published literature range from 42 to 75, meaning that participants on average had the highest level of shared decision-making that has been reported.[22]

[f] Decision Self-efficacy Scale scores range from 0 to 100, with higher scores indicating greater self efficacy. The mean score in a recent US study was 76.7, suggesting that participants had higher decision self-efficacy than has been reported.[23]

[g] Satisfaction With Decision Scale scores range from 0 to 5, with higher scores indicating more satisfaction. The mean score in prior published work was 3.9, meaning that participants were more satisfied on average than has been reported in other clinical populations.[24]

finding. In the sensitivity analysis conducted after exclusion of 82 women who developed contraindications to trial of labor after cesarean delivery (64 with breech presentation and 18 with placenta previa), results for trial of labor (adjusted absolute risk difference, -2.39% [95% CI, -7.57% to 2.79%]; adjusted relative risk, 0.95 [95% CI, 0.85-1.06]) were similar to those of the main analysis results. Post hoc analysis showed no significant difference in trial-of-labor rates based on the gestational age when the tool was viewed (adjusted absolute risk difference per week, 0.25% [95% CI, -0.82% to 1.32%]; adjusted relative risk per week, 1.01 [95% CI, 0.98-1.03]). Results of the analyses using multiple imputation did not differ from those obtained in the primary and secondary analyses (eTables 2 and 3 in Supplement 2).

Discussion

In this study of women with 1 prior cesarean delivery and no prior vaginal birth after cesarean delivery, there were no statistically significant differences in rates of trial of labor and vaginal birth or in decision quality when women randomized to use a patient-centered decision support tool were compared with women randomized to receive usual care. Overall, study participants experienced relatively high trial-of-labor and vaginal birth rates and good decision quality regardless of exposure to the decision tool.

There are reasons to expect that the decision regarding trial of labor after cesarean delivery as opposed to elective repeat cesarean delivery could benefit from a decision support intervention. This decision has been recognized as one in which values placed on the maternal and perinatal risks of each option vary, and a shared decision-making approach is recommended.[10,28] Moreover, engagement in and documentation of the informed consent process is not always adequate.[9,29] The decision requires consideration—complex numerically and in terms of value determination—of common but undesired outcomes (trial of labor ending in uncomplicated cesarean delivery) as well as rare events with devastating implications (uterine rupture resulting in maternal or neonatal adverse outcome).[12,28,30] Although clinicians and patients have online access to the validated calculator used in the tool, how frequently it is used in clinical practice and how effective clinicians are at integrating the generated information into a recommendation are not known.[31] In addition, while low rates of trial of labor and vaginal birth after cesarean delivery are occurring throughout the US, racial/ethnic, geographic, and socioeconomic differences persist,[1,32] raising concern about the effectiveness and patient-centeredness of approach to delivery after cesarean delivery. Such issues could be addressed by improved, reliable, and consistent approaches to shared decision-making.[33]

Several aspects of the findings suggest that participants made decisions concordant with their values: (1) the high rates of trial of labor; (2) the similarity between the proportion of women inclined toward trial of labor at enrollment (47.6%) and the proportion of those eligible for this approach who opted for it at delivery (44.8%); and (3) the high level of

decision quality reported. A survey of women a year after their first birth found that 45% of those who had undergone a cesarean delivery desired a vaginal delivery for their next birth, which is similar to both the reported preferences in the study population and the rate of trial of labor after cesarean delivery observed.[34] Given the high rates of trial of labor and vaginal birth and good decision quality, further increasing the trial-of-labor rate in the study population may not be appropriate or desirable, as it may already reflect the true informed preference-based demand for this delivery approach.[35] Whether use of this tool would lead to different outcomes in populations with different initial preferences or outcome frequencies is not known.

Four smaller studies of decision tools in the setting of prior cesarean delivery have demonstrated improved decision quality by a variety of metrics[36-39]; however, only 1 resulted in increased vaginal birth rates.[37] The current study, which has a larger sample size than the 4 prior studies combined, and is the only one performed in a contemporary US population using usual care as a comparator, suggests that further increases in settings where rates of trial of labor after cesarean delivery and decision quality are both relatively high may not occur.

Strengths of this study include the randomized evaluation of a decision support tool that is evidence based and patient centered and was designed using a methodologically rigorous process.[11] Other strengths include the sample's diversity, the high recruitment and retention rates, and the completeness of the data.

Limitations

This study had several limitations. First, the relatively high rate of trial of labor in both randomization groups limits generalizability of the findings. Second, the decision tool was used before 25 weeks' gestation based on recommendations that decisions regarding delivery approach should start early in pregnancy; whether the results would be different if it were used at a different time during pregnancy cannot be determined. Third, the study was underpowered to detect potentially clinically significant differences in outcomes with low frequencies. Fourth, although the sample was geographically and racially/ethnically diverse, participants had a high educational attainment and were mostly partnered and being cared for in academic medical centers.

Conclusions

Among women with 1 previous cesarean delivery, use of a decision support tool compared with usual care did not significantly change the rate of trial of labor. Further research may be needed to assess the efficacy of this tool in other clinical settings or when implemented at other times in pregnancy.

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Concept and design: Kuppermann, Kaimal, Bryant, Bacchetti, Grobman.
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Drafting of the manuscript: Kuppermann, Kaimal.
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